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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/985,756	11/06/2001	Matthew C. Coffey	032775-083	4370

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EXAMINER

YAO, LEI

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 08/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/985,756

Applicant(s)

COFFEY, MATTHEW C.

Examiner

Lei Yao, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Arguments

The Amendment filed on 5/9/05 in response to the previous Non-Final Office Action (12/13/05) is acknowledged and has been entered.

Claims 11-50 have been cancelled.

Claims 1-10 are pending and under consideration. Claim 5 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Claims 1-4 and 6-10 are under consideration.

The following office action contains NEW GROUNDS of rejection.

The following is New Ground of rejections

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 6-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al., (WO 99/08692, published 2/25/1999).

Claim 1 is drawn to a method of determining susceptibility of a cell to reovirus infection by measuring constitutive ras-MAP signaling in the cell, wherein the presence of the constitutive signaling indicated susceptibility to infection by reovirus. Claim 4 is further drawn to claim 1, wherein the cell comprising in a biological sample collected from a mammal suspected of having a proliferative disorder. Claims 6-10 are further drawn to claim 4, wherein the disorder is human breast cancer.

Lee et al., disclose a method of determining susceptibility of a cell to reovirus infection by measuring the reovirus infection efficiency in the transformed cells with c-myc gene. Lee et al., teach that

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susceptibility to reovirus infection is not due to the general transformed state of the host cell, but rather require specific transformation by elements of the Ras signaling pathway, which would have constitutive ras-MAP signaling in the cells. Lee et al., also disclose that the activation of the Ras signaling pathway is the activation of the MAP kinases ERK1 and ERK2 (page 18, line 5-11). Lee et al., further disclose that correlation between the levels of ERK1/2 activity and susceptibility to reovirus infection is revealed after examination of a number of human cancer lines including mouse L cells and human Hela cells, in which reovirus grows very well, both manifest high ERK ½ activity (page 18, line 14-18). Lee et al., also disclose measuring the MAP kinase (ERK) activity by an antibody specific for phosphorylated MAP kinase (page 12, line 3-12).

Claim 1, 4, 6-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Strong et al., (The EMBO J, vol 17, pare 3351-62, 1998).

Claims 1, 4, 6-10 are set forth above.

Strong et al., disclose a method of determining susceptibility of a cell to reovirus infection by measuring the reovirus infection efficiency in the transformed cells with c-myc gene (Tet-myc cells). Strong et al., disclose that susceptibility to reovirus infection is not due to the general transformed state of the host cell, but rather require specific transformation by elements of the Ras signaling pathway. Strong et al., also disclose that the activation of the Ras signaling pathway is the activation of the MAP kinases ERK1 and ERK2 (page 3353, column 2 and page 3354, column 1). Strong et al., further disclose that correlation between the levels of ERK1/2 activity and susceptibility to reovirus infection is revealed after examination of a number of human cancer lines and mouse L cells and human Hela cells, in which reovirus grows very well, both manifest high ERK ½ activity (page 3354, column 1, start at line 5). Strong et al., also disclose measuring the MAP kinase (ERK) activity by an antibody specific for phosphorylated MAP kinase (page 3360, column 2, para 2).

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Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 and 6-10 rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al., and Strong et al., as applied to claims 1, 4 and 6-10 above, and further in view Nguyen et al., (J Bio Chem, vol 146, page 149-164).

The teaching by Lee et al., and Strong et al., are set forth above.

Lee et al., and Strong et al., do not teach the ras-MAP signaling is measured by determining the state of phosphorylation of MAP kinase.

Nguyen et al., teach a method of measuring ras-MAP signaling by determining the phosphorylation of MAP (ERK1/2) kinase in breast cancer cells. Nguyen et al., teach that the phosphorylation of ERK1/2 kinase is measured by antibody specific for phosphorylated ERK1/2 (page 150, column 2, para 1 and page 154, figure 3A)

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to use the method of Lee et al., or Strong et al., comprising determining susceptibility of a cell to reovirus infection by measuring constitutive ras-MAP signaling in the cells by determining the state of MAP kinase phosphorylation taught by Nguyen et al. One of ordinary skill in the art would have been motivated with a reasonable expectation of success to combine the teaching of Lee et al., or Strong et al., to the teaching of Nguyen et al., to use the method to determine the susceptibility of a cell to reovirus infection by measuring constitutive ras-MAP signaling in the cells because Lee et al., or Strong et al., have suggested that susceptibility to reovirus infection is due to the constitutive ras-MAP signaling in the breast cancer cells and Nguyen et al., have shown a method of measuring the ras-MAP signaling in the cell by determining the state of the phosphorylation of MAP (ERK1/2) kinase.

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Rejections Withdrawn

The rejections of claims 1-4 and 6-10 under 35 USC § 103 are withdrawn in view of the applicant argument and references.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.


Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
9/22/05